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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.           | CONFIRMATION NO. |
|---|-------------|----------------------|-------------------------------|------------------|
| 10/076,514  | 02/19/2002  | Ludwig Volkel        | 52203                         | 3431             |
| 7590  | 02/09/2004  |                      |                               |                  |
| Herbert B. Keil<br>KEIL & WEINKAUF<br>1101 Connecticut Ave., N.W.<br>Washington, DC 20036 |             |                      | EXAMINER<br>YOUNG, MICAH PAUL |                  |
|   |             |                      | ART UNIT<br>1615              | PAPER NUMBER     |

DATE MAILED: 02/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |                                      |  |
|------------------------------|--------------------------------------|--------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/076,514 | <b>Applicant(s)</b><br>VOLKEL ET AL. |  |
|                              | <b>Examiner</b><br>Micah-Paul Young  | <b>Art Unit</b><br>1615              |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 November 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

**Acknowledgement of Papers Received:** Amendment/Response filed

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Spires (USPN 4,394,377 hereafter referred to as '377). The claim is drawn to a choline abscorbate in form of crystals.

'377 discloses crystalline choline salts made with organic and inorganic acids.

According to '377, the crystalline salts including choline abscorbate are available commercially (col. 3, lin. 62 – col. 4, lin. 7). The crystals can be incorporated into ruminant animal supplement (col. 4, lin. 28 – 35) These disclosures render the claims anticipated.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 3-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Spires (USPN 4,394,377 hereafter referred to as '377) and Klein et al (USPN 2,870,198 hereafter referred to as '198). The claims are drawn to a choline ascorbate crystal and a process for making.

As discussed above '377 discloses a crystalline choline ascorbate. '377 also discloses other crystalline salts of choline including choline citrate and bitartrate, however does not disclose the process by which the crystals are formed. Crystallization is a common form of isolation well known in the art. Isolation with ethylene oxide and trimethylamine, at low temperature is well known in the art as seen in '759 (col. 2, lin. 18 – 59). Organic acids such as anhydrous citric acid are used in the reaction (examples). It would be within the level of skill in the art to produce the choline ascorbate of '377 by the process of '198 by substituting ascorbic acid as the organic acid.

With regard to claims 3 – 5 which recite the diffraction characteristics of the compound, it is the position of the examiner that these characteristics would be inherent to the compound recited in the art. Presented here is a crystalline choline ascorbate free from water of crystallization, and processed from reacting ascorbic acid, trimethylamine and ethylene oxide, at a temperature below 40°C. Barring a showing of unexpected results or evidence to the contrary it is the position of the examiner that the compounds of the present invention and the compound recited by the art are identical, hence having identical properties including diffraction

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characteristics. The diffraction information claimed can be determined through routine experimentation by artisans of ordinary skill and do not impart patentability on the formulation.

Also the Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. *See Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

With these things in mind a skilled artisan would have been motivated to process the crystalline choline abscorbate by the process of '198 with a simple substitution of the organic acid. As seen by '377 the crystals are useful as dietary supplements for ruminant animals. A skilled artisan would have been motivated make the crystals in this way in order to yield a crystal of higher purity. '337 establishes a relationship between choline citrate and abscorbate salts. '198 teaches a method of making choline citrate salt crystals. A skilled artisan would be able to substitute abscorbate into the preparation. It would have been obvious to a skilled artisan to combine these teachings and suggestions with an expected result of a substantially pure crystalline choline abscorbate with pharmaceutical applications.

***Correspondence***

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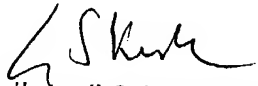
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Micah-Paul Young  
Examiner  
Art Unit 1615

MP Young

  
Gollamudi S. Kishore, PhD  
Primary Examiner  
Group 1600

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